

REMARKS

In response to the Requirement for Restriction dated December 3, 2009, applicants respond as follows:

Applicants provisionally elect with **traverse** from the Species of tissue section preparation, Species B (Claims 31, 32);

Applicants provisionally elect with **traverse** from the Species of non-morphological analytical testing, Species D (Claims 40, 41);

Applicants provisionally elect with **traverse** from the Species of treatment of biological molecules, Species F (Claims 47, 49);

Applicants provisionally elect with **traverse** from the Species of histological/cytological examination, Species H (Claims 50, 51); and

Applicants provisionally elect with **traverse** from the Species of using the method, Species L (Claim 59, 60) for further prosecution in the above captioned application.

Applicants enter the above elections provisionally, and request the reconsideration and withdrawal of the election/restriction requirement. The requirement is **traversed** for the following reasons.

At the outset, it is noted that the Examiner relies upon PCT Rule 13.1 for the requirement, stating that the alleged different “species lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.” (Requirement, pg. 2). Applicants respectfully disagree.

Under the PCT, the concept of “lack of unity of invention” means that allegedly different inventions are present, which means that the allegedly different inventions lack a “common

technical feature”. See MPEP §1893.03(d) (“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.”).

In the first instance, it is noted that each of the claims to which the Restriction Requirement has been applied is a dependent claim, depending from either claim 24 or claim 25. Thus, even under the Examiner’s interpretation, there are currently pending independent generic claims (claims 24 and 25) that respectively embrace each of the delineated “species”.

As explained in Chapter 10 of the International Search and Preliminary Examination Guidelines, a lack of unity of invention exists only if the allegedly different inventions lack a common *special technical feature*. However, even though two dependent claims which depend from a single independent claim may claim different structure, they nonetheless present common technical features, *see, especially*, Example 12 of the International Search and Preliminary Examination Guidelines, ¶ 10.32:

Claim 1: A display with features A + B.
Claim 2: A display according to claim 1 with additional feature C.
Claim 3: A display with features A + B with additional feature D.
Unity exists between claims 1, 2 and 3. The special technical feature common to all of the claims is features A + B.

The Examiner asserts that unity of invention does not exist because the independent claims do not avoid the prior art, specifically U.S. Pub. No. 2003/0186248 (“*Erlander*”). Applicants traverse this assertion.

Independent claim 24 recites “wherein in the histological/cytological examination, at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect of

the at least one of the prepared sections is determined by an image processing system”. Claim 25 recites a corresponding limitation. *Erlander* fails to teach or suggest this limitation.

The Examiner asserts that *Erlander* discloses “wherein in the histological/cytological examination, at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect of the at least one portion of the sample is determined by an image processing system” at paragraphs 25, 39 and 64. Even assuming, *arguendo*, that *Erlander* discloses that image analysis may be used to identify cells of interest, *Erlander* fails to teach or suggest that one quantitative fraction of diseased tissue or cells and another morphological aspect of the at least one portion of the sample is determined by an image processing system, as recited in independent claim 24, and correspondingly recited in independent claim 25.

Erlander (paragraph, [0025], lines 1-6) explains that “[i]n addition to comparisons with ‘reference’ histological signatures of different disease stages, the present invention provides for comparisons of molecular signatures of cytological specimens with ‘reference’ histological signatures of different subtypes of a disease condition as phenotypes”. *Erlander* (paragraph [0039], lines 1-7) additionally explains that “[u]se of microdissection is a preferred aspect of the invention because contaminating, non-disease related cells (such as infiltrating lymphocytes or other immune system cells) may be eliminated from a cytological specimen or histological sample to avoid the possibility of affecting the biomolecules identified or the subsequent analysis thereof to identify the status of suspect cells. *Erlander* [0039], lines 7-14) further explains that “[s]uch contamination is present where a biopsy is used to generate a gene expression profile as a ‘reference’ signature without further isolation of cancer related cells (such as by microdissection). Contamination may also be obviated by use of a molecular signature that is not

affected by contaminating, non-disease cells, such as via detection of expression of one or more biomolecules that are not expressed in contaminating cells”.

Erlander describes methods for collecting cytological specimens. According to *Erlander*, “[i]n the case of breast cancer, such specimens include fine needle aspirates and ductal lavage which can be used to prepare cytological smears or a ThinPrep®” (see lines 3-6 paragraph [0064]). However, paragraphs [0025], [0039] and [0064] of *Erlander* each fail to teach or suggest the special technical features of independent claims 24 and 25. That is, there is no teaching or suggestion of an image processing system that is implemented in the manner recited in independent method claims 24 and 25.

PCT Rule 13.2 explains that “[w]here a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art”.

Claim 24 embodies a single general inventive concept, which involves a method of analyzing a patient tissue sample to determine a fraction of diseased tissue while essentially preserving at least one of genomic property, proteomic property, epigenomic property and biophysical property of the tissue sample ... “wherein in the histological/cytological examination, at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect of the at least one of the prepared sections is determined by an image processing system”.


Independent claim 25 also involves a method of analyzing a patent tissue sample to determine a fraction of diseased tissue while essentially preserving at least one of genomic property, proteomic property, epigenomic property and biophysical property of the tissue sample ... wherein in the histological/cytological examination, at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect of the at least one portion of the sample is determined by an image processing system”.

There is no teaching or suggestion whatsoever in *Erlander* of the foregoing *special technical features* recited in independent claims 24 and 25. Therefore, claims 24 and 25 relate to a single general inventive concept, and possess a technical relationship among these inventions involving one or more of the same or corresponding *special technical features*. Therefore, it is respectfully requested that the requirement be withdrawn.

In the event that the requirement is maintained, the above provisional elections are made with traverse, while the applicants maintain their right to seek rejoinder upon the allowance of a generic claim.

Applicants reserves the right to pursue the non-elected claims in a divisional application prior to issuance of a patent on the instant application.

Respectfully submitted,
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